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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------|------------------|
| 10/679,722  | 10/06/2003  | Duane D. Miller      | 20609/203 (PD 00034) | 2869             |
| 7590  | 04/06/2006  |                      | EXAMINER             |                  |
| Nixon Peabody LLP<br>Clinton Square<br>P.O. Box 31051<br>Rochester, NY 14603-1051 |             |                      | AULAKH, CHARANJIT    |                  |
|   |             |                      | ART UNIT             | PAPER NUMBER     |
|   |             |                      | 1625                 |                  |

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/679,722             | MILLER ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Charanjit S. Aulakh    | 1625                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 March 2006.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-44 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. _____.   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

### **DETAILED ACTION**

1. According to paper filed on March 27, 2006, the applicants have filed a RCE and furthermore, have amended claim 1.
2. Claims 1-44 are pending in the application.

### ***Response to Arguments***

3. Applicant's arguments filed on March 27, 2006 have been fully considered but they are not persuasive regarding enablement and indefiniteness rejections. In regard to enablement rejection, the examiner does not agree with the applicants arguments that the specification on pages 16-18 teaches various disease conditions where alpha-2a and alpha-2c receptors have been implicated. As stated clearly in the last office actions, the instant compounds are antagonists at these receptor subtypes based on the data in the instant specification. However, there is no teaching in the specification on pages 17-19 whether antagonists of alpha-2a or alpha-2c receptors are well known in the prior art to have therapeutic utility in treating hypertension, hypotension, erectile dysfunction, pain, glaucoma, alcohol and drug withdrawal, rheumatoid arthritis, ischemia, migraine, cognitive deficiency, spasticity, diarrhea, nasal congestion and Raynaud's disease. There are no working examples present in the instant specification showing efficacy of instant compounds in known animal models of hypertension, hypotension, erectile dysfunction, pain, glaucoma, alcohol and drug withdrawal, rheumatoid arthritis, ischemia, migraine, cognitive deficiency, spasticity, diarrhea, nasal congestion and Raynaud's disease. The applicants have not provided any prior art references showing well known utility of structurally closely related compounds in treating hypertension,

hypotension, erectile dysfunction, pain, glaucoma, alcohol and drug withdrawl, rheumatoid arthritis, ischemia, migraine, cognitive deficiency, spasticity, diarrhea, nasal congestion and Raynaud's disease. Also, there is no teaching or guidance in the specification how to assess central versus peripheral effects of instant compounds following their in vivo administration specially when used for treating high or low blood pressure since stimulation of central versus peripheral alpha-2a receptors have opposite effects on the blood prerssure.

In regard to indefiniteness rejections, the examiner does not agree with the applicants arguments that claims are definite since applicants have amended claim 1 to recite specific diseases. It is not clear from the claim language whether specific listed disease conditions are solely mediated by agonist or antagonist activity at alpha-2a or alpha-2c receptors. It is well known in the art that there are multiple mechanisms involved in the etiology of any disease condition including instant disease conditions. There is no disease condition known in the art which is specifically mediated by agonist or antagonist activity at only one receptor subtype such as alpha-2a or alpha-2c. In regard to instant claims 24-44, the applicants argue that receptor will be inhibited both in vitro and in vivo. However, in order for the compound to inhibit specific receptor in vivo, the compound needs to be administered. However, there is no mention of administering the instant compounds for in vivo inhibition. Also, what is the end result of this inhibition?

### ***Conclusion***

4. Rejections under 35 U.S.C. 112, first paragraph and second paragraph are maintained for the reasons of record.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571)272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625